REMARKS

In the Office Action, claims 1, 11, 15, 16, 44 and 52 are rejected under 35 U.S.C. § 102; and claims 1-82 are rejected under 35 U.S.C. § 103. Applicants believe that the rejections are improper based on at least the reasons set forth below.

With respect to the rejection of claims 1, 11, 15, 16, 44 and 52, the Patent Office alleges that U.S. Patent No. 5,122,516 ("Watanabe") anticipates, or in the alternative, renders obvious the subject matter as defined therein. Of these claims, claims 1 and 44 are the sole independent claims. Claim 1 recites a two part dialysis solution that includes a first component and a second component wherein the first component includes a bicarbonate concentrate and the second components includes an electrolyte concentrate and wherein each of the first and second components includes a physiological acceptable amount of sodium. Claim 44 recites a method of providing hemofiltration to a patient. The method includes providing a first component that includes a bicarbonate concentrate and a second component that includes an electrolyte concentrate wherein each of the first component and the second component includes a physiological acceptable amount of sodium; mixing the first and second components to form a mixed solution; and using the mixed solution during hemofiltration.

The solution components of the bicarbonate-based solutions as claimed can be readily and sterily mixed to form the resulting bicarbonate-based solution. Applicants have discovered that the bicarbonate-based solutions of the present invention can eliminate the need of excessive handling of one more of its components prior to mixing as compared to conventional solutions which may necessarily require a physician or other medical care provider to manually inject one or more components, such as bicarbonate, potassium chloride and the like, during the formulation of a bicarbonate solution.

In this regard, the ready-to-use bicarbonate based formulations of the present invention can decrease the amount of time and effort with respect to the preparation and administration of the formulations of the present invention as compared to conventional bicarbonate formulations. The ready-to-use formulations of the present invention can also effectively eliminate, or at least greatly minimize, the potential of the spread of biological contamination during the preparation, administration and/or general use thereof. This is desirable particularly as applied in medical therapies conducted in an intensive care setting including during hemofiltration, such as

continuous renal replacement therapy, to treat critically ill patients for acute renal failure. See, Specification, for example, page 7, lines 4-20.

Applicants believe that Watanabe is distinguishable from the claimed invention. At the outset, the focus of Watanabe relates to a preparation for blood dialysis. See, Watanabe, Abstract. Indeed, nowhere does Watanabe provide for the use of its preparation as a replacement fluid, an infusion fluid or the like during hemofiltration, such as continuous renal replacement therapy.

As claimed, the two part solutions include a bicarbonate concentrate and an electrolyte concentrate wherein each include a physiological acceptable amount of sodium. This physiological acceptable level of sodium can be achieved by distributing sodium chloride between the bicarbonate concentrate and the electrolyte concentrate as further supported in the specification on page 10 at lines 19-23. As previously discussed, the solution components of the bicarbonate-based solutions as claimed can be readily mixed to form a ready-to-use formulation that can effectively eliminate, or at least greatly minimize, the potential of the spread of biological contamination during the preparation administration and/or general use thereof. This is particular important as applied to medical therapies conducted in intensive care settings, such as during hemofiltration, including, for example, continuous renal replacement therapy, as further defined in claim 44. Again, the emphasis of Watanabe relates to more traditional dialysis therapies, particularly hemodialysis, that are known to have limited use with respect to intensive care applications, such as with respect to the treatment of critically ill patients for acute renal failure. See, Specification, page 1, lines 8-15. Based on at least these reasons, Applicants believe that Watanabe fails to anticipate or render obvious the subject matter in claims 1 and 44 and claims 11, 15, 16 and 52 that depend therefrom.

Accordingly, Applicants respectfully request that the rejection in view of Watanabe on its own be withdrawn.

The Patent Office also alleges that claims 1-82 are rejected under 35 U.S.C. § 103 in view of U.S. Patent No. 5,871,477 ("Isono") and further in view of Watanabe, U.S. Patent No. 4,630,727 ("Feriani") and van Bommel. The Patent Office primarily relies on Isono and thus relies on the combination of the remaining cited references to remedy the deficiency of same.

Applicants believe that the cited art even if combinable is distinguishable from the claimed invention. At the outset, the Patent Office merely cites to the primary Isono reference for its alleged teaching regarding a two part dialysis composition containing bicarbonate and

electrolyte, in which a portion of the electrolyte, for example, sodium, can be in the bicarbonate part. See, Office Action, page 3. In contrast, a number of the claims, such as independent claims 17, 30, 55 and 64, recite two part solutions, in part, with potassium in at least one of the bicarbonate and electrolyte concentrates.

Further, nowhere does Isono emphasize whether a physiological acceptable amount, let alone an equamolar amount of sodium, should be contained in both the bicarbonate and electrolyte solution components. Indeed, some of the claims (e.g., independent claims 1, 44, 73 and 77) require, in part, that a physiological acceptable amount of sodium, such as an equimolar amount including about 160 mmol/L or less, is provided in both the bicarbonate and electrolyte solution concentrates. As further supported in the specification, sodium chloride can be distributed between the bicarbonate concentrate and the electrolyte concentrate such that each contains an equimolar and physiological acceptable concentration of sodium. See, Specification, page 10, lines 19-23.

As previously discussed, the solution components of the bicarbonate-based solutions as claimed can be separately housed such that the components can be readily and sterily mixed to form ready-to-use bicarbonate-based solutions. This can decrease the amount of time and effort with respect to the preparation and administration of such formulations as compared to conventional bicarbonate formulations. This can also effectively eliminate, or at least greatly minimize, the potential of the spread of biological contamination during the preparation, administration and/or general use thereof. This is particularly important as applied to medical therapies conducted in intensive care settings, such as during hemofiltration including, for example, continuous renal replacement therapies. Indeed, the emphasis of the Isono reference relates to a medical container with an electrolyte solution stored therein (see, Isono, Abstract) that can be used in peritoneal dialysis as further illustrated on Figure 13 in Isono. Peritoneal dialysis and other forms of traditional dialysis therapies, such as hemodialysis, may have limited use in intensive care settings as compared to hemofiltration including continuous renal replacement therapy. See, Specification, page 1, lines 7-16. Therefore, Isono on its own is clearly distinguishable from the claimed invention for at least these reasons.

Further, Applicants do not believe that the remaining cited references, even if properly combinable, can remedy the deficiencies of Isono. With respect to Watanabe, this reference provides mere optional ingredients in contrast to the solutions as claimed. See, generally, Watanabe, Abstract. For example, Watanabe discloses potassium as an optional ingredient, for

example, in column 2 at line 61. This clearly contrasts the subject matter as defined, for example, in claims 5, 17 and 55. Each of these claims recites, in part, that the electrolyte concentrate includes potassium. The claimed solution components can then be readily and sterilely mixed to form a ready-to-use solution for effective use. Moreover, this can provide an added safety feature where the potassium cannot be placed in direct fluid communication with a patient without mixing with the other components of the solution as further supported in the specification, for example, on page 11, at lines 7-19.

With respect to sodium content, the Watanabe reference is, at a minimum, deficient with respect to sodium at equimolar levels in both the electrolyte and bicarbonate concentrates in contrast to claims 2, 3, 19, 45, 46, 57, 73, 74, 77 and 78. For example, the Watanabe reference provides that the sodium content ranges from 90 to 140 mmols in the first composition (electrolyte) and ranges from 15 to 40 mmols in the second composition (bicarbonate) as disclosed in columns 2 and 3, for example, of Watanabe.

The Watanabe reference also fails to place any mixing constraints on how the composition is prepared, let alone how it is administered during use. This clearly contrasts the subject matter as defined, for example, in claims 17 and 55. Indeed, claim 17 recites, in part, that the first component and the second component are so constructed and arranged that the second component physically cannot be infused into the patient without mixing with the first component; and claim 55 recites, in part, that the first component and second component are oriented so that the second component physically cannot be infused into the patient without mixing with the first component. This promotes the safe and effective use of the bicarbonate-based solutions as claimed and further supported in the specification, for example, on page 11 at lines 20-31.

Moreover, nowhere does Watanabe provide for the use of its preparation with respect to hemofiltration including continuous renal replacement therapy as previously discussed. Thus, the emphasis of Watanabe relates to more traditional dialysis therapies, particularly hemodialysis, in contrast to the subject matter as defined, for example, in claims 16, 17, 44, 55 and 77 that relates to hemofiltration. Therefore, Watanabe on its own cannot remedy the deficiencies of Isono.

Contrary to the Patent Office's position, Applicants do not believe that Feriani and van Bommel can remedy the deficiencies of Osono and Watanabe. For example, Feriani provides sodium in the bicarbonate concentrate but not in the electrolyte concentrate. See, Feriani, col. 6, lines 15-27. Potassium is also provided as an optional ingredient in the bicarbonate concentrate

as disclosed in Feriani in column 6 at line 25. Indeed, this teaches away from the claims that require, in part, potassium in at least one of the bicarbonate and electrolyte concentrates. Moreover, the Patent Office has merely relied on van Bommel for its purported teachings regarding hemodialysis and continuous renal replacement therapy.

What the Patent Office has done is to rely improperly on hindsight reasoning in support of the obviousness rejection. With the addition of Isono, now the Patent Office relies on four references in support of the obviousness rejection. Again, Isono is deficient with respect to the claimed invention for at least a number of reasons where the Patent Office merely relies on Isono for its alleged teaching regarding a two part dialysis composition with bicarbonate and electrolyte concentrates wherein sodium can be in the bicarbonate part. The remaining other references, even if properly combinable, cannot be relied on solely to remedy the deficiencies of Isono as previously discussed. Indeed, the Patent Office even admits that the cited art does not describe a two-part composition with potassium in both the bicarbonate and electrolyte parts. Therefore, Applicants do not believe that one skilled in the art would be motivated to modify Isono to cover the claimed invention based on the teachings of the remaining other references.

Accordingly, Applicants respectfully request that the obviousness rejection of claims 1-82 be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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